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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,197	01/30/2004	Gianni Plicchi	P08156US00/MP	4582

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STITES & HARBISON PLLC
1199 NORTH FAIRFAX STREET
SUITE 900
ALEXANDRIA, VA 22314

EXAMINER	
KOTINI, PAVITRA	
ART UNIT	**PAPER NUMBER**
3731	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/767,197	PLICCHI ET AL.	
	Examiner	Art Unit	
	Pavitra Kotini	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,17-24 and 28-31* is/are rejected.

7)☒ Claim(s) *12-16,25-27 and 32-39* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/20/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use since there are no appropriate sections and headings in the specification.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.

(b) CROSS-REFERENCE TO RELATED APPLICATIONS.

(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.

(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.

(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.

(f) BACKGROUND OF THE INVENTION.

(1) Field of the Invention.

(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.

(g) BRIEF SUMMARY OF THE INVENTION.

(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).

(i) DETAILED DESCRIPTION OF THE INVENTION.

(j) CLAIM OR CLAIMS (commencing on a separate sheet).

(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).

(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Applicant is reminded of the proper language and format for an abstract of the disclosure. The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Claim Objections

Claim 10 is objected to under 37 CFR 1.75(c) as being in improper form because it is a multiple dependent claim. See MPEP § 608.01(n). Accordingly, claim 10 has not been further treated on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically regarding claim 1 and many of the dependent claims, the phrase "for example" has been used numerous times and renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d). furthermore, claim 1 and all dependent claims are replete with functional language, which have been carefully considered but are not given patentable weight because the disclosed prior art is capable of performing the desired function. Regarding claim 2, the limitation "metal stylet" lacks sufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9, 11, 17-23, 28-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Brock et al. (US-2002/0087169).

Brock discloses an apparatus for the maneuvering of flexible catheters in the human cardiovascular system, characterized in that it comprises:

Regarding **claim 1**, means (fig.6, 13), in the form of an arm for example, for positioning, aiming and correct orientation with respect to the patient of a device (26) for remote manipulation of the catheter (30); A device (26) which supports at least one portion of the catheter (para. 0096, 0112) and which comprises remotely controllable actuators (pulleys 62 and 74), for transmitting to the said catheter at least a longitudinal movement of advance or withdrawal and/or a rightward or leftward rotary movement about its longitudinal axis; A control and monitoring unit (master station 1 or surgeon's interface 11) located in a remote position and protected in a shielded environment, by means of which the operator can remotely control and monitor the operation of the said device which carries out the servo-controlled maneuvering of the catheter in the patient's body (para. 0095, 0099, 0111-0112); Means (slave station 13) for the operational remote connection of the said servo-controlled device to the said control and monitoring unit (master station 1 and control unit 2; para.0097).

Regarding **claim 2**, means which, in response to a remote command from the said control unit (11), can execute a controlled forward or backward longitudinal movement and if necessary a rightward or leftward rotation of the metal stylet (34) normally present in the catheter (30), to facilitate and correct the advance of the said catheter in the patient's body (para.0095, 0173).

Regarding **claim 3**, a disposable device (para. 0221 discloses any tools be made disposable) for the ligature of the access vessel (tools for ligature are disclosed in para.

0137) for the introduction of the catheter, which has the function of controlling the haemostasis and/or supporting the end of the said vessel into which the catheter (30) is to be inserted (para.0018 discloses a disposable electronically controlled surgical instrument, which is capable of being any one of tools 18 listed in para.0137), while allowing the catheter to undergo the necessary sliding and rotary movements (catheter 30 can be moved forward and backward and rotated; para.0174), this device being supported by suitable means (salve station 3 and drive unit 13) and being , for example, associated with means which enable the closing tension of the ligature exerted on the vessel to be increased or reduced by remote control (controller or computation system 12) from the control and monitoring unit (user interface 11) located in the protected booth (user interface 11 and drive unit 13 are located remotely, outside the sterile surgical field; para.0097-0099).

Regarding **claim 4**, all the parts intended to come into contact with the catheter (30) and with any corresponding stylet (34) are provided in a disposable component (para.0015-0018, 0221) designed for rapid and removable mounting on a box (fig. 6, 26) which contains all the actuators and means necessary for the operation of the said apparatus by remote control.

Regarding **claim 5**, the catheter is of the steerable type, and the said apparatus comprises means driven by remotely controllable actuators, also housed in the box (26) containing the drive equipment (pulleys), these actuators guiding the said catheter by transmitting to the tip and to the body of the said catheter the necessary bending and/or

rotation to reach the desired position within the cardiovascular system (para. 0095, 0182, 0184; fig. 19).

Regarding **claims 6-9 and 17**, as best understood by the Examiner, the claim is not limited to the rollers or belts, but can include any equivalent means (note phrase: "or equivalent means" on line 14). Therefore, the specifics of the rollers and belts are not necessarily required. Brock discloses control elements (64, 72) which move the outer shat 32 and inner shaft 34, which in turn rotate the tool at the end of the shaft.

Regarding **claim 11**, the catheter manipulation device (26) comprises at least one specific set of rollers or belts (pulley 64; para. 0182) for the longitudinal movement of the catheter, and a different set of rollers or belts (pulley 72; para.0184) expressly designed to rotate the said catheter about its longitudinal axis.

Regarding **claim 18**, safety means (para.0116-0126) are provided that provide inpu tto the user similar to during direct manipulation of the catheter.

Regarding **claim 19**, means are provided in the remote shielded station (master unit 1) from which the operator operates with the unit (user interface 11) for controlling and monitoring the said apparatus through a video system (para. 0007, 0012).

Regarding **claim 20**, means for measuring important physical parameters of the patient being treated are also provided in the remote shielded station from which the operator operates with the remote control and monitoring unit (11) of the said apparatus (para. 0116).

Regarding **claim 21**, said apparatus (26) and the ligature device for controlling haemostasis can be connected to an interface system suitable for communication over

a distance with the control unit (11) located in the remote shielded room in which the operator operates, by means of wire-based or wireless connection and/or communication systems (ligature system is connected to master unit and controlled remotely; para. 0137-0141).

Regarding **claim 22**, the systems for the remote control of the said apparatus can comprise voice control systems (para. 0115).

Regarding **claim 23**, the means, of the arm type (fig. 6) for example, for positioning the said apparatus with respect to the patient are such that they remain fixed when the said apparatus operates, or can be movable and adjustable by remote control (drive unit 13 comprises catheter 30 which moves; para.0101).

Regarding **claim 24**, it is old and well known in the art that there be a backup power source, especially for medical devices, in the case of an emergency. See for example US patent # 6533757, 5938623, 5813997, and 5704912.

Regarding **claim 28**, the catheter (30) has an internal stylet (34) acting as a guide mandrel, the said robotic apparatus is provided with two maneuvering units (24, 26), each of which can transmit rightward or leftward movements and longitudinal forward and backward movements to the catheter (30) and to the guide mandrel (para.0101, 0185).

Regarding **claim 29**, maneuvering unit (24, 26) carriers rollers (64, 72) which grip catheter and can be driven selectively and independently (para.0182, 0184), both in respect of the longitudinal movement and the rotation of the said catheter (30) and or the guide mandrel (34).

Regarding **claims 30 and 31**, the pair of rollers (64, 72) interact with the catheter (30). It is old and well known in the art that the rollers can be made of suitable material for gentle frictional interaction and that catheters can be made of or covered on their circumference with an elastomeric material, especially in order to prevent damage to vessel walls, among many other advantages. For example, see US patent 5437659, 5026366, 6139570.

Allowable Subject Matter

Claims 12-16, 26, 27, 32-39 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 12-16, 26, 27, 32-39 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Brock et al. (US- 2002/0138082) discloses a operator's interface remotely located and controlled via a mechanical drive mechanism. Disposable elements are also disclosed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pavitra Kotini whose telephone number is 571-272-0624. The examiner can normally be reached on M-F 8:30am to 6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

P.Kotini
AU 3731

ANHTUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
4/30/07